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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/783,092

02/23/2004

Taru Blom

03426.000140.

3520

5514 7590 11/19/2007
FITZPATRICK CELLA HARPER & SCINTO
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NEW YORK, NY 10112

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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11/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/783,092

Applicant(s)

BLOM ET AL.

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☒ Claim(s) 6-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed **5/02/07** presents remarks and arguments to the office action mailed **1/19/07**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

Claims 1 and 3-13 are pending in this office action.

Claim 1 has been amended and claim 2 cancelled.

Claim Objections

Claims 1 and 11 are objected to because of the following informalities: The abbreviations TORE and TRAP5b should be defined or spelled out when first used. Appropriate correction is required.

Allowable Subject Matter

Claims 6-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

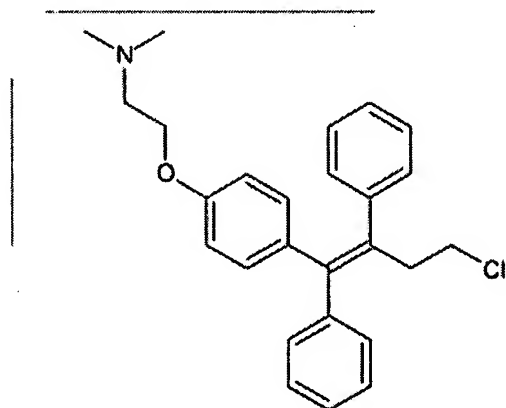
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marttunen et al., Calcified Tissue International, 65:365-368 (1999) taken with Kangas, Cancer Chemotherapy and Pharmacology, 27:8-12 (1990).

Marttunen et al. teach administration of toremifene



Toremifene

having a core structure that is the same as the

claimed compound of formula I, to ascertain bone resorption in postmenopausal breast cancer patients by measuring bone resorption markers, as required by instant claims 1 and 4. See abstract, underlining. With regard to claim 5, the reference suggests bone an increase bone turnover is detected. See abstract and page 367, underlining. The reference, however, fails to teach the exact claimed compound of instant claim 1.

Kangas teaches different forms or metabolites of toremefine as TORE, TORE II, V, IV etc. See page 9, Fig. I.

One of ordinary skill in the art would have been motivated to administer TORE VI, which is the same as the claimed compound of formula I to patients suffering from increased bone turnover known as bone loss. Therefore, one of ordinary skill in the art would have been motivated to administer a metabolite of toremifene such as ospemifene (compound of formula I) as claimed and taught as TORE VI to patients with increased bone loss. Kangas teaches the metabolites of toremifene to be biologically active and to resemble toremifene in its hormonal effects. It would have been

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reasonable to expect a decrease in bone loss because Kangas reference teaches toremifene metabolites are inclusive of ospemifene.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Maintained Double Patenting

Claim 1 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1- 9 of U.S. Patent Application No. 11/183185. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

Both sets of claims refer to treating an individual suffering from increased bone turnover – decrease bone loss in the current application (claim 1) and androgen deficiency (claims 1-9) in the copending application. The current application claims anticipate the copending application claims. As to the copending application

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claims 1-9, these claims refer to treating androgen deficiency in a male with the claimed compound ospemifene with several deficiencies. One such deficiency of this type is bone loss an obvious variant of the claimed subject matter as evidenced by claim 9, for example.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

Applicants' amendment to the claim does not overcome the above rejection because, when the specification is used as a dictionary, the compound of formula I is used for treating decreased bone density in androgen deficiency in a male.

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
1/09/07

~~ARDIN H. MARSCHEL~~
~~SUPERVISORY PATENT EXAMINER~~
Ardin H. Marschel 1/10/07
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